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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/648,196 08/25/00 KIM

M 3066/FLK

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HM12/0418

EXAMINER

FOLEY, S

ART UNIT

PAPER NUMBER

1648

DATE MAILED:

04/18/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/648,196

Applicant(s)

KIM ET AL.

Examiner

Shanon A. Foley

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Objections*

Claims 12-20 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). However, in the interest of compact prosecution, the claims are considered to be dependent from claim 1.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-5, 7, and 10-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Maniar et al. in WO 92/14449.

The claims are drawn to a lipophilic microparticle comprising a drug, such as a growth hormone, or an antigen. The lipophilic substance is derived from a fatty acid, such as palmitic acid. The microparticle is in a water-soluble excipient in a lipophilic medium, such as vegetable oil and further comprises a buffered solution that is injected.

Maniar et al. teaches a delivery vehicle comprising a fatty acid of stearic acid (see example 1 and 9 on pages 8 and 10, respectively) or palmitic acid (see example 7 on page 10) and biologically active proteins, such as growth hormone and therapeutically active peptide. The

Art Unit: 1648

desired particle size can range between 10-400  $\mu$  (see the last see the paragraph bridging pages 6-7) that is suspended in a solution that can be injectable (see the first full paragraph on page 7).

Prolonged *in vivo* activity is achieved by suspending the microparticles in vegetable or mineral oil, see the third full paragraph on page 7. See also claims 1-3 and 5-10. The teachings of Maniar et al. anticipate claims 1-4, 7, and 10-18.

Claims 1-6, 8-12, 15, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Poli et al. in US 5,759,566.

Poli et al. teaches a lipophilic microparticle comprising a drug or an antigen, see column 4, lines 20-68. The lipophilic substance is derived from a fatty acid, such as lecithin, see example 4 in column 5, or hyaluronic acid, see column 5, example 3. The microparticle is in a water-soluble excipient in a lipophilic medium, and further comprises a buffered solution and preservatives, see column 3, line 56 through column 4, line 19. Also see claims 1, 12, 16, 17, 20, and 21. The teachings of Poli et al. anticipate claims 1-6, 8-12, 15, and 20.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poli et al.

Although Poli et al. does not expressly teach administering multiple antigens in the microparticle, one of ordinary skill in the art at the time the invention was made would have been motivated to incorporate a plurality of antigens into the microparticle system because the

Art Unit: 1648

bioavailability of these microparticles is comparable to that administered parenterally, see column 4, line 20-28. Therefore, one skilled in the art would have a reasonable expectation of producing the claimed invention and achieving results comparable to other conventional methods. From the teachings of the references, the invention as a whole is prima facie obvious, absent unexpected results.


### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on 7:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley  
April 13, 2001

  
**MARY E. MOSHER  
PRIMARY EXAMINER  
GROUP 1800**